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TAFT, STETTINIUS & HOLLISTER LLP
SUITE 1800
425 WALNUT STREET
CINCINNATI, OH 45202-3957

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAY C. WASIELEWSKI

Appeal 2009-007472
Application 10/612,784
Technology Center 3700

Decided: April 21, 2010

Before: LINDA E. HORNER, WILLIAM F. PATE III, and STEVEN D.A. MCCARTHY, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellant appeals under 35 U.S.C. § 134 (2002) from a rejection of claims 1, 2, 4-6, 14, 15, 27-32 and 37. App. Br. 3. We have jurisdiction under 35 U.S.C. § 6(b) (2008).

The claims are directed to the use of snap-on semiannular augments to inhibit multi-directional instability after total hip arthroplasty. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:
>
> an acetabular liner for releasably engaging an acetabular cup permanently mounted to the patient's pelvis; and
>
> a semiannular augment to be mounted to a rim of an acetabular liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular liner, at least temporarily, between the acetabular liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem;
>
> the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and
>
> wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent; and
>
> wherein the augment material is formulated not to transform into scar tissue.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Mikhail	5,549,701	Aug. 27, 1996
Klüber	DE 197 16 051 A1	Nov. 13, 1997

REJECTIONS

Claims 1, 2, 4-6, 14, 15, 27-32, and 37 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Ans. 3. Claims 109 and 110 have been cancelled. App. Br. 3; Ans. 2.

Claims 1, 2, 4-6, 14, 15, 27-32, and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Klüber or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Klüber and Mikhail. Ans. 4-5.

The Examiner withdrew the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 102(b). Ans. 6, 7; Reply Br. 7.

ISSUES

The first issue raised by Appellant is whether the Examiner erred by finding that the claim phrase "wherein the augment is formulated not to transform into scar tissue" lacks descriptive support in the original disclosure. App. Br. 11-15; Reply Br. 2-5.

For the grounds of rejection under § 103, claims 1, 2, 4-6, 14 and 15 are argued as a group. App. Br. 20-22. Claims 27-32 and 37 are also argued as a group. App. Br. 23-24. In both groups Appellant contends that the Examiner erred by finding Klüber discloses an augment material that "is

formulated not to transform into scar tissue." Thus, the first issue related to the obviousness rejection for our consideration is whether the Examiner erred by finding Klüber discloses an augment material that "is formulated not to transform into scar tissue." In the second group of claims Appellant contends at least three limitations are not disclosed by Klüber. However, Appellant argues only two limitations, App. Br. 23-24, one of which is the augment material "formulated not to transform into scar tissue" allegedly missing from the first group of claims. Appellant additionally contends that Klüber fails to disclose "at least one integrated fastener" because Klüber's screw, read by the Examiner as the claimed "fastener," is not "integrated." App. Br. 23; Ans. 67, 10. It is noted that this limitation also appears in claim 14, although claim 14, along with dependent claim 15, are included in the first claim grouping. Thus, the next issue for our consideration is whether the Examiner erred by interpreting Klüber's screw as "at least one integrated fastener." Appellant does not contest the Examiner's conclusion that it would have been obvious to modify Klüber to account for the perceived differences between the prior art and the claimed subject matter. Ans. 5. Appellant also does not contest any of the Examiner's findings or conclusions pertaining to Mikhail. Ans. 5-6.

FINDINGS OF FACT

1. The Specification provides:

> [0040] In the exemplary embodiment utilizing the biologically reabsorbable snap-on augments 26, such augments 26 could be formulated to [be] absorbed over a relatively short period (i.e., several weeks or months) and could also be formulated so as to be replaced by tissue (such as scar-tissue) that would provide for long-term hip stability and, hopefully, normal motion. Such

> formulations of biologic materials are well known by those of ordinary skill in the art.
>
> [0041] As will be apparent to those of ordinary skill in the art there are many other biologic and/or biologically reabsorbable materials that can be used for the snap-on augments 26 or snap clips 28, and there are also new biologic materials being developed on a consistent basis, all of which fall within the scope of the invention.

2. The Specification provides that an example of a biologically reabsorbable material that can be used for the augments 26 is poly-L-lactic acid (PLLA). P. 11, para. [0041]; p. 12, para. [0043].
3. As discussed in detail below, the Specification lacks descriptive support for an "augment material [] formulated not to transform into scar tissue."
4. Klüber, as translated from the original German, discloses a resorbable luxation securing ring (A), made of PLLA that prevents dislocation during the healing phase and "is transformed into yielding connective tissue." P. 1, para. 1; p. 2, paras. 3 and 6.
5. Klüber discloses that screws C are received in holes G to secure the retaining ring A to the socket component B. P. 2, para. 5.

PRINCIPLES OF LAW

The Written Description Requirement of 35 U.S.C. § 112, first paragraph

New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. *See, e.g., In re Lukach*, 442 F.2d 967 (CCPA 1971). The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the

applicant for a patent is therefore required "to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)). While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64. When an explicit limitation in a claim is not present in the written description it must be shown that a person of ordinary skill would have understood that the description requires that limitation. *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). If the originally filed disclosure does not provide support for each claim limitation, a new or amended claim must be rejected under 35 U.S.C. § 112, first paragraph as lacking adequate written description. Whether a specification complies with the written description requirement of 35 U.S.C. § 112, first paragraph, is a question of fact. *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (citing *Vas-Cath, Inc.*, 935 F. 2d at 1563). The Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). Claim construction is an essential element in determining adequacy of the written description. (*See e.g.*, MPEP § 2163).

35 U.S.C. § 103(a)

The Supreme Court in *KSR* reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The factual inquiries set forth in *Graham* that are to be applied to establish a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Graham, 383 U.S. at 17-18.

Claim construction is the first step in an obviousness analysis. *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998) (citations omitted). A patent applicant is free to recite features of an apparatus either structurally or functionally. *See In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971). "Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk." *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). As stated in *Swinehart*:

> where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

439 F.2d at 213.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *See e.g., In re Schreiber*, 128 F.3d at 1477-78.

ANALYSIS

The rejection of claim 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement is affirmed.

The Examiner correctly concluded that the phrases "formulated to be replaced by" and "transformed into" differ in scope. Ans. 7. No express definitions are provided in the Specification for these terms. They are given their ordinary and customary meaning. To "replace" a material means to remove the original material and substitute new material in its place. THE AMERICAN HERITAGE® DICTIONARY OF THE ENGLISH LANGUAGE (2000). To "transform" a material means to change the original material into a new material. *Id.* At best, Appellant's premise, that the term "could" in paragraph [0040] (*see* Fact 1) inherently implies "could or could not," might support a claim directed to augments that are "not formulated to be replaced by scar tissue." If Appellant wished to cover the same scope as the Specification, the same language could have been employed. While there is no *in haec verba* requirement regarding descriptive support in the Specification, taking into consideration the differing scope of the phrases "replaced by" and "transformed into," the newly added limitation encompasses subject matter outside the scope of the Specification as originally filed.

Appellant's argument that the newly added limitation only literally recites inherent properties of materials described in the Specification, such as PLLA, is not supported by the facts of record. App. Br. 14; Reply Br. 4; Fact 2. Firstly, the Matsusue article, submitted for the first time with the Reply Brief is not timely. 37 C.F.R. § 41.33(d). Secondly, the mere disclosure of PLLA alone is not sufficient to provide descriptive support for a material that is formulated "not to transform into scar tissue." Appellant himself contends the exact opposite in arguing the prior art rejections, asserting that the mere fact that Klüber discloses a single ingredient, PLLA, in the augments is irrelevant to whether Klüber discloses augment material that is formulated not to transform into scar tissue. App. Br. 21. The fact that one of ordinary skill in the art would know how to employ PLLA to formulate an augment material that does not transform into scar tissue is relevant to the enablement requirement but not to the separate written description requirement. *See Ariad Pharms., Inc. v. Eli Lilly and Co.*, ___ F.3d ___, 2010 WL 1007369, at *6 (Fed. Cir. Mar. 22, 2010). A description that merely renders the invention obvious does not satisfy the written description requirement. *See id.* at *14 (citing *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)). Appellant is improperly attempting to claim a particular result without describing the structure that accomplishes it. *See id.* (citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927-28 (Fed. Cir. 2004)).

For these reasons we adopt the Examiner's finding that the Specification lacks descriptive support for an "augment material [] formulated not to transform into scar tissue." Fact 3. The Examiner has explained that the claimed embodiment lies outside the scope of the

Specification and has reasoned that mere disclosure of PLLA does not suffice to support this limitation. Thus, the Examiner has established a prima facie case.

The rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 103(a) as being unpatentable over Klüber or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Klüber and Mikhail is affirmed.

Klüber discloses an augment material that "is formulated not to transform into scar tissue." Firstly, even if Klüber does describe a transformation of the PLLA, there is no indication that the transformation is into "scar tissue." Klüber discloses the material is transformed into "yielding connective tissue." Fact 4. There is no evidence of record establishing that the "yielding connective tissue" described by Klüber is "scar tissue."

Secondly, the Examiner reasonably concluded that since Klüber's retaining ring is structurally indistinguishable from Appellant's claimed augment, Klüber's retaining ring would act in the same manner as Appellant's augment when placed in the body and "not [be] transformed into scar tissue." Ans. 5. The fact that the translator chose the term "transform" to describe the process undergone by Klüber's material is not dispositive. The same word may have different meanings in different contexts and the prior art must be considered as a whole. Klüber provides no additional details of what exactly is meant by "transform." Unlike Appellant, Klüber does not also employ the term "replace" which would tend to indicate recognition of distinct meanings. Since the Examiner has a reasonable basis to believe that the limitation asserted by Appellant to be critical for

establishing novelty in the claimed subject matter is, in fact, an inherent characteristic of Klüber, the burden shifts to Appellant to establish that this belief is erroneous. *Swinehart*, 439 F.2d at 213. Appellant has not provided sufficient evidence to do so.

Regarding the term "integrated," a predecessor to our reviewing court on several prior occasions interpreted the term "integral" to cover more than a unitary construction. *See, e.g.*, *In re Kohno*, 391 F.2d 959, 960 n.4 (CCPA 1968); *In re Dike*, 394 F.2d 584, 590 (CCPA 1968); *In re Larson*, 340 F.2d 965, 967-68 (CCPA 1965); *In re Clark*, 214 F.2d 148, 150 (CCPA 1954). The Federal Circuit has also endorsed this interpretation. *See, e.g.*, *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 887 F.2d 1070, 1074 (Fed. Cir. 1989) (nothing of record limited "integral" to mean "of one-piece" construction). Appellant has not pointed to any definition in the Specification or elsewhere which would mandate that the term "integrated fastener" be afforded such a narrow construction so as to exclude Klüber's screws contained within the holes bored in the retaining ring. *See* Fact 5. Appellant's own fasteners 28 are not described as being of unitary construction with the augment, and the Specification describes that "[s]crew mechanisms" may be used. Spec., para. [0032]. Thus, Appellant's argument that Klüber fails to disclose "at least one integrated fastener" is not persuasive.

Appellant's "teaching away" argument is noted (App. Br. 24), but lacking from this argument is any reasoning to show that Klüber criticizes, discredits, or otherwise discourages the solution claimed—fundamental to establish that a reference "teaches away." *See, e.g.*, *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

DECISION

The rejection of claim 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 103(a) as being unpatentable over Klüber or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Klüber and Mikhail is affirmed.

The rejection of claim 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2009).

AFFIRMED

nhl

TAFT, STETTINIUS & HOLLISTER LLP
SUITE 1800
425 WALNUT STREET
CINCINNATI OH 45202-3957